PSY41

REVIEW OF HOME READINESS INSTRUMENTS TO ASSESS RECOVERY POST-SURGERY

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OBJECTIVES: Minimising post-surgery length of stay is important to patients, clinicians and payers who want to optimise recovery rates and minimise costs. However, evaluating new products and procedures using actual length of stay is influenced by hospital payment incentives, organisational structures and socio-economic factors. This study aimed to identify instruments to measure post-anaesthesia home readiness and evaluate their suitability for use in a clinical trial. **METHODS:** A literature review was carried out to identify published evidence including home readiness instruments. Medline, Embase and Biosis databases were searched for RCTs and instrument-specific publications. The internet was searched for health technology assessments, economic evaluations and guidelines. An inventory of instruments was compiled and, for each, the suitability of use in a clinical trial setting was assessed in terms of previous examples of use in a clinical trial, evidence of validation and reliability, compatibility with other recovery measures, supporting information and application to an in-patient setting. **RESULTS:** Fifteen papers provided evidence of the use of the Post-Anaesthetic Discharge Scoring System (PADS) [1] in a variety of trial settings and validation work. Nine papers referred to other instruments measuring home readiness but no other instrument had been used in more than one trial or validated. The British Association of Day Surgery referred to PADS in their published guidelines. There was an example of PADS in an economic evaluation of fast-tracking recovery [2]. **CONCLUSIONS:** PADS was found to be the most appropriate instrument for assessing home readiness as it has undergone more validation than other identified measures and there is evidence of its use in multiple RCTs. [1] Chung et al. A post-anesthetic discharge scoring system for home readiness after ambulatory surgery. J Clin Anesth 1995;7:500–6; [2] Song et al. Fast-tracking (by-passing the PACU) does not reduce nursing workload after ambulatory surgery. Br J Anaesth 2004;93:768–4.

SYSTEMIC DISORDERS/CONDITIONS— Patient-Reported Outcomes Studies

PSY42

E-DIARY COMPLIANCE IN ACUTE PAIN STUDIES

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OBJECTIVES: In acute pain studies, subjects are asked to report on symptoms at specific intervals after dosing. One or more assessments are often primary endpoints. When timed assessments are collected on paper the actual time the assessments were completed is unknown, and enforcing completion of the assessment at a specific time is impossible. Electronic patient reported outcome technologies (ePRO) allow control over the window in which a subject can complete the electronic diary (e-Diary), and a time stamp associated with diary completion. E-Diaries assure the investigator of more reliable information: the 120 minute assessment was completed at or near 120 minutes. But is there a down side? With a restricted window of time for completing an e-diary in the acute pain model, how compliant will subjects be? **METHODS:** Diary completion was examined in 12 randomized clinical trials using the acute pain model. Indications were surgical pain, migraine, or break through pain. Subjects completed pain diaries at timed intervals after dosing. In 4 trials, subjects completed at least some of the assessments in the clinic or post surgical area allowing comparison of compliance in supervised settings to compliance with e-diaries at home. Frequency of the assessments varied across the trials, allowing some description of factors which may influence compliance. Finally, design features, like a reminder alarm, were correlated with time of diary compliance to understand the usefulness of these features. **RESULTS:** e-Diary compliance in supervised setting can be as high as 100%. Compliance in unsupervised settings is typically 80%, although frequent assessments correspond with decreased compliance. In one study that required extensive frequent assessments, e-Diary compliance is much lower. Indication does not correlate with e-Diary compliance in unsupervised settings. **CONCLUSIONS:** Factors that correspond with e-diary compliance are supervision, frequency and overall demand on subjects.

PSY43

THE IMPACT OF ROMIPLOSTIM ON PATIENT-REPORTED OUTCOMES MEASURED BY THE EUROQOL (EQ-5D)

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OBJECTIVES: The study objective was to estimate health status changes using the EuroQol (EQ-5D) in immune thrombocytopenia purpura (ITP) patients treated with romiplostim in two, 24-week randomized placebo controlled phase 3 trials. **METHODS:** The EQ-5D was scored from 0 to 1 for both the summary score (Index) and the visual analog scale (VAS) and was given at baseline and every four weeks thereafter. Patients received either romiplostim (titrated to maintain platelets between 50 to 200×10^9/L) or placebo at a 2:1 ratio. One trial was conducted in patients (n = 62) with ITP without splenectomy and the other was among patients (n = 63) refractory to splenectomy. We pooled data across studies and evaluated the EQ-5D change from baseline to week 24. We compared romiplostim with placebo, as well as responders with non-responders. Responders had mean platelet counts $\geq 50 \times 10^9$/L for 6 of the last 8 weeks on the study (regardless of treatment group). Effects were estimated using linear regression (final score as the dependent variable adjusting for baseline score). Responder analyses incorporated age and gender as covariates. Missing follow up data were imputed using the last available value, unless a subject died, in which case zero was imputed. Patients with insufficient data were excluded (n = 11). **RESULTS:** At baseline the median age was 52 years (range 21 to 88), 65% were females, 82% were white, and the mean platelet count was 16.5×10^9/L. The differences in mean change from baseline for romiplostim compared to placebo was 0.06 for the Index ($p = 0.017$) and 0.05 for VAS ($p = 0.040$). Adjusted mean changes were similar for responders versus non-responders (0.06 and 0.10 for the Index and VAS, $p < 0.05$). **CONCLUSIONS:** Romiplostim use was associated with significant improvement in health status. Furthermore, these results will be useful for assessing the value of romplostim in economic models.

PSY44

UNDERSTANDING AND ASSESSING THE IMPACT OF PRESCRIPTION WEIGHT LOSS MEDICATION; CONCEPTUAL, GENDER AND CULTURAL ISSUES

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OBJECTIVES: As obesity becomes a global epidemic, the use of weight loss medications (WLM) continues to increase. The